

MAR 7 - 2005

**510(k) SUMMARY**

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

**Submission Information**

Contact: Seayoung Ahn, Dr.  
7612 Barnum Road, Bethesda, MD 20817

Sponsor: Solco Biomedical Co., Ltd  
34-6 Keumam-ri, Seotan-myeon,  
Pyeongtaek, Gyeonggi-do, 451-852  
Republic of Korea

Date Prepared: 23 December 2004

**Device Identification**

Trade Name: 4CIS<sup>®</sup> Spinal System and 4CIS<sup>®</sup> Low Back System

Common Name: Pedicle Screw Spinal Fixation System

Classification Name: Spondylolisthesis Spinal Fixation Device System(MNH)  
per 21 CFR § 888.3070,  
Spinal Pedicle Screw(MNI) per 21 CFR § 888.3070

**Substantially Equivalent Predicate Legally Marketed Devices**

The subject device, 4CIS<sup>®</sup> Spinal System and 4CIS<sup>®</sup> Low Back System, is substantially equivalent in the function, design, composition, material and intended use to devices:

Global Spinal Fixation System(K001668), and OPTIMA<sup>™</sup> Spinal System(K031585)

**Device Description**

The 4CIS<sup>®</sup> Spinal System and 4CIS<sup>®</sup> Low Back System are a top-loading multiple component, posterior spinal fixation systems which consist of pedicle screws, rods, locking spacer, and a transverse (cross) linking mechanism.

The 4CIS<sup>®</sup> Spinal System and 4CIS<sup>®</sup> Low Back System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The 4CIS<sup>®</sup> Spinal System and 4CIS<sup>®</sup> Low Back System implant components are supplied in the non-sterile condition for a single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to the ASTM F136. Various sizes of these implants are available. Specialized instruments are also available for the application and

**Solco Biomedical Co.,Ltd**

4CIS<sup>®</sup> Spinal System/4CIS<sup>®</sup> Low Back System 510(k) Submission

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removal of the 4CIS<sup>®</sup> Spinal System and 4CIS<sup>®</sup> Low Back System.

### **Indications for Use**

The 4CIS<sup>®</sup> Spinal System and 4CIS<sup>®</sup> Low Back System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by the autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the 4CIS<sup>®</sup> Spinal System and 4CIS<sup>®</sup> Low Back System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with the objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

### **Performance Data**

Mechanical testing as listed in **APPENDIX 10** that was conducted in accordance with ASTM F1717 demonstrates the substantial equivalence to the above predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 7 - 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Solco Biomedical  
c/o Dr. Saeyoung Ahn  
7612 Barnum Road  
Bethesda, Maryland 20817

Re: K043578  
Trade/Device Name: 4CIS® Spinal System and 4CIS® Low Back System  
Regulation Number: 888.3070(b)(1)  
Regulation Name: Pedicle Screw Spinal System  
Regulatory Class: Class II  
Product Code: MNH, MNI  
Dated: December 28, 2004  
Received: December 28, 2004

Dear Mr. Ahn:

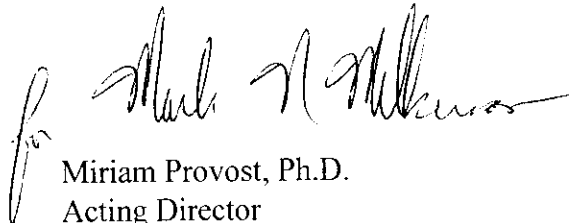
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam Provost", is written over a large, faint, stylized letter "f" that serves as a signature guide.

Miriam Provost, Ph.D.  
Acting Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K 043578

Device Name: 4CIS® Spinal System & 4CIS® Low Back System

### Indications for Use:

The 4CIS® Spinal System & 4CIS® Low Back System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the 4CIS® Spinal System/4CIS® Low Back System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRL, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number

K 043578